

U.S. Application No.: NEW
PRELIMINARY AMENDMENT

JC17 Rec'd PCD/PTO 16 JUN 2005

Attorney Docket: 4007.009

IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claims 1-26 (canceled)

27. (new) A method for diagnosis of carcinomas and their precursor lesions and/or prognosis of disease course comprising
- a) obtaining a cell containing tissue sample from an individual
 - b) determining the level and/or subcellular localization of DNase-X molecules in the cells of said tissue;
 - c) comparing the level and/or subcellular localization of DNase-X molecules within said sample to the contents within a corresponding control sample, not affected by the disease being tested;
 - d) wherein the diagnosis or prognosis of disease course is predicted from considering a significant increased level relative to the wild type level of DNase-X molecule in said tissue sample and/or cellular nuclei as indicative of said disorder or of the prognosis of the disease course.
28. (new) The method according to Claim 1, wherein the detection of the DNase-X molecules comprises the detection of the accessibility of particular regions of the DNase-X molecules.

29. (new) The method according to Claim 1, wherein the sample is selected from a group comprising blood, plasma, serum, liquor, lymph, bone marrow, swabs, washes, lavages, secretions, transsudates, exsudates, sputum, stool, urine, semen, cell- and tissue-samples, punctuates or biopsies.
30. (new) The method according to Claim 1, wherein the carcinoma is selected from a group comprising cancer of the head and the neck, cancer of the respiratory tract, cancer of the gastrointestinal tract, cancer of the skin and its appendages, cancer of the central and peripheral nervous system, cancer of the urinary system, cancer of the reproductive system, cancer of the endocrine system, cancer of the soft tissues and bone, cancer of the lymphopoietic and hematopoietic system, breast cancer, lung cancer, cervical cancer, colorectal cancer or anogenital cancer.
31. (new) The method according to Claim 1, wherein the detection of the level of the DNase-X molecule is carried out using at least one probe specifically binding to the marker molecules to be detected.
32. (new) The method according to Claim 5, wherein the probe is detectably labelled.

33. (new) The method according to Claim 6, wherein the label is selected from the group consisting of a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, a metal chelate, a biologically relevant binding structure such as biotin or digoxigenin or an enzyme.
34. (new) The method according to Claim 5, wherein at least one probe is an antibody, a fragment of an antibody, a peptidomimetic comprising an antigen binding epitope or a mini-antibody.
35. (new) The method according to Claim 8, wherein the detection comprises an immuno-cytochemical detection procedure.
36. (new) The method according to Claim 5, wherein at least one probe being a nucleic acid hybridising to a marker nucleic acid is used for the detection of the DNase-X marker molecules.
37. (new) The method according to Claim 10, wherein the detection reaction comprises a nucleic acid amplification reaction.
38. (new) A probe for cancer, the probe comprising a probe specifically binding to or reacting with DNase-X and being

capable of indicating amount and/or concentration and/or localisation of DNase-X in a tissue sample or a sample containing cells and/or cell fragments and/or cell nuclei.

39. (new) A method of identifying and obtaining a drug candidate for therapy carcinomas and their precursor lesions comprising the following steps:
- a) contacting a DNase-X polypeptide or a cell expressing said polypeptide in the presence of components capable of providing a detectable signal in response to DNase-X activity, cell proliferation or cell differentiation with said drug candidate to be screened under conditions to allow DNase-X activity, cell proliferation or changes in cell differentiation and
 - b) detecting presence or absence of a signal or increase of the signal generated from DNase-X activity, cell proliferation or cell differentiation, wherein the presence or increase of the signal is indicative for a putative drug.
40. (new) Kit for the detection and/or treatment of carcinomas and their precursor lesions, comprising at least DNase-X or a compound selected from a group comprising
- a) a binding partner to a DNase-X polypeptide;
 - b) an activators/agonists or inhibitors/antagonists of a DNase-X polypeptide;
 - c) an activator or inhibitor of the expression of a DNase-X polypeptide; and

- d) a drug candidate as described in Claim 13.
41. (new) Pharmaceutical composition useful for treating carcinomas and their precursor lesions comprising at least DNase-X or a compound selected from a group comprising
- a) one or more DNase molecules being nucleic acids or polypeptides;
 - b) one or more activators/agonists or inhibitors/antagonists of a DNase polypeptide;
 - c) one or more activators or inhibitors of the expression of a DNase polypeptide;
 - d) one or more binding partners of DNase polypeptides; and
 - e) or one or more drug candidates as described in Claim 13;
- for production of a.
42. (new) The pharmaceutical composition according to Claim 15, wherein the carcinoma is selected from a group comprising cancer of the head and the neck, cancer of the respiratory tract, cancer of the gastrointestinal tract, cancer of the skin and its appendages, cancer of the central and peripheral nervous system, cancer of the urinary system, cancer of the reproductive system, cancer of the endocrine system, cancer of the soft tissues and bone, cancer of the lymphopoietic and hematopoietic system, breast cancer, anogenital cancer or colorectal cancer.